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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	10/719,007	
Sheet	1	of	6	Filing Date	November 20, 2003
				First Named Inventor	JOHNSON, RANDOLPH MELLUS
				Group Art Unit	1614
				Examiner Name	To be assigned
				Attorney Docket Number	DURE-007CON2

U.S. PATENT DOCUMENTS						
Examiner Initials ¹	Cite No. ¹	U.S. Patent Documents		Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, columns, lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
2		Re. 36,547		Crain et al.	02-01-00	
		4,681,560		Schulte et al.	07-21-1987	
		4,692,147		Duggan	09-08-1987	
		5,798,114		Elsberry et al.	08-25-1998	
		3,141,823		Jan Janssen et al.	07-21-1964	
		3,760,984		Theeuwes	09-25-1973	
		3,845,770		Theeuwes et al.	11-05-1974	
		3,916,899		Theeuwes et al.	11-04-1975	
		3,923,426		Theeuwes	12-02-1975	
		3,987,790		Eckenhoff et al.	10-26-1976	
		3,995,631		Higuchi et al.	12-07-1976	
		3,998,834		Janssen et al.	12-21-1976	
		4,016,880		Theeuwes et al.	04-12-1976	
		4,036,228		Theeuwes	07-19-1977	
		4,111,202		Theeuwes	09-05-1978	
		4,111,203		Theeuwes	09-05-1978	
		4,167,574		Janssens	09-11-1979	
		4,203,440		Theeuwes	05-20-1980	
2		4,203,442		Michaels	05-20-1980	

Examiner Signature	<i>Lis Ghol-</i>	Date Considered	6/21/05
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				Group Art Unit	1614
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		4,210,139		Higuchi	07-01-1980	
		4,327,725		Cortese et al.	05-04-1982	
		4,360,019		Portner et al.	11-23-1982	
		4,487,603		Harris	12-11-1984	
		4,576,951		Rovati et al.	03-18-1986	
		4,582,835		Lewis et al.	04-15-1986	
		4,627,850		Deters et al.	12-09-1986	
		4,725,852		Gamblin et al.	02-16-1988	
		4,769,372		Kreck	09-06-1988	
		4,781,924		Lee et al.	11-01-1988	
		6,245,351		Nara et al.	06-01-2001	
		4,588,580		Gale et al.	05-13-1999	
		6,203,813		Gooberman	03-20-2001	
		4,865,845		Eckenhoff et al.	09-12-1989	
		5,057,318		Magruder et al.	10-15-1991	
		5,059,423		Magruder et al.	10-22-1991	
		5,112,614		Magruder et al.	05-12-1992	
		5,137,727		Eckenhoff	08-11-1992	
		5,180,716		Yaksh et al.	01-19-1993	
		5,187,177		Garzaran	02-16-1993	
		5,234,692		Magruder et al.	08-10-1993	
		5,234,693		Magruder et al.	08-10-1993	
		5,346,903		Ackerman et al.	09-13-1994	
		5,356,635		Raman et al.	10-01-1994	
		5,451,408		Mezei et al.	09-19-1995	

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J		5,472,943		Crain et al.	12-05-95	
		5,486,362		Kitchell et al.	01-23-1996	
		5,487,739		Acbischer et al.	01-30-1996	
		5,512,578		Crain et al.	04-30-96	
		5,580,876		Crain et al.	12-03-96	
		5,633,000		Grossman et al.	05-27-1997	
		5,660,854		Haynes et al.	08-26-1997	
		5,672,167		Athayda et al.	09-30-1997	
		5,729,396		Dudley et al.	03-17-1998	
		5,747,058		Tipton et al.	05-05-1998	
		5,767,125		Crain et al.	06-16-98	
		5,798,114		Elsberry et al.	08-25-98	
		5,980,927		Nelson et. al..	11-09-1999	
		5,985,305		Peery et al.	11-16-1999	
		5,858,388		Grossman et al.	01-12-1999	
J		6,096,756		Crain et al.	08-01-00	
		6,436,091		Hamer et al.	08-20-2002	
		6,541,021		Johnson et al.	04-01-2003	
		6,689,373		Johnson et al.	02-10-2004	

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				Filing Date	November 20, 2003
				First Named Inventor	JOHNSON, RANDOLPH MELLUS
				Group Art Unit	1614
				Examiner Name	To be assigned
Sheet	4	Of	6	Attorney Docket Number	DURE-007CON2

FOREIGN PATENT DOCUMENTS								
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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
JP		WO	99/36071		Lee et al.	07-22-1999		
JP		WO	97/49391		Sackler et al.	12-31-1997		
JP		WO	97/27840		Perry et al.	08-07-1997		
JP		WO	98/51246	A	Elkhoury et al.	11-19-1998		

OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS			
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JP		Ahmedzai (1997), "New approaches to pain control in patients with cancer." <i>Eur. J. Cancer</i> , 33(6):S8-S14.	
JP		Anderson <i>et al.</i> (1998), "Alternate routes of opioid administration in palliative care: pharmacologic and clinical concerns." <i>J. Pharmaceut. Care Pain Symp. Control</i> , 6:5-21.	
JP		Bansinath, <i>et al.</i> (1989). "Hyperglycemia does not modify the pupillary effects of μ and κ opiate Agonists in mice" <i>J. Ocular Pharmacology</i> , Vol. 5(1): 33-43.	
JP		Bruera <i>et al.</i> (1987). "Use of the subcutaneous route of the administration of narcotics in patients with cancer pain" <i>Cancer</i> , Vol. 62(2): 407-411.	
JP		Cherny <i>et al.</i> (1995). "Opioid pharmacotherapy in the management of cancer pain" <i>Cancer</i> , Vol. 76(7): 1283-1293.	
JP		Clotz <i>et al.</i> (1991). "Clinical uses of fentanyl, sufentanil, and alfentanil" <i>Clinical Pharmacy</i> , Vol. 10: 581-593.	

Examiner Signature	<i>Lois Ghali</i>	Date Considered	6/21/05
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Filing Date	November 20, 2003
		First Named Inventor	JOHNSON, RANDOLPH MELLUS
		Group Art Unit	1614
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(use as many sheets as necessary)		Attorney Docket Number	DURE-007CON2
Sheet	5	of	6

OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
P		Coda <i>et al.</i> (1997). "Comparative efficacy of patient-controlled administration of morphine, hydromorphone, or sufentanil for the treatment of oral mucositis pain following bone marrow transplantation" <i>Pain</i> , Vol. 72: 333-346.	
		Coyle <i>et al.</i> (1994), "Subcutaneous opioid infusions at home." <i>Oncology</i> , 8:21-27.	
		Crane (1994). "Intermittent subcutaneous infusion of opioids in hospice home care: An affective, economical, manageable option" <i>Am. J. Hospice & Palliative Care</i> , Vol. Jan/Feb: 8-12.	
		Dhasmana <i>et al.</i> (1987). "Gastrointestinal transit following intrathecal or subcutaneous narcotic analgesics" <i>Arch. Int. Pharmacodyn.</i> , Vol. 286: 152-161.	
		Fine (1997), "Fentanyl in the treatment of cancer pain." <i>Sem. Oncol.</i> , 24(16):S16-S27.	
		Finley (1990), "Pain management with spinally administered opioids." <i>Am. J. Hosp. Pharm.</i> , 47(1):S14-S17.	
		Fuginaga <i>et al.</i> (1988). "Reproductive and teratogenic effects of sufentanil and alfentanil in Sprague-Dawley rats" <i>Anesth Analg</i> , Vol. 67: 166-169.	
		Geller <i>et al.</i> (1993). "A randomized double-blind comparison of epidural sufentanil versus intravenous sufentanil or epidural fentanyl analgesia after major abdominal surgery" <i>Anesth Analg</i> , Vol. 76: 1243-1250.	
		Jeal <i>et al.</i> (1997), "Transdermal fentanyl. A review of its pharmacologic properties and therapeutic efficacy in pain control." <i>Drugs</i> , 53:109-138.	
		Kerr <i>et al.</i> (1988), "Continuous narcotic infusion with patient-controlled analgesia for chronic cancer pain in outpatients." <i>Ann. Intern. Med.</i> , 108:554-557.	
		Kingery (1997), "A critical review of controlled clinical trials for peripheral neuropathic pain and complex regional pain syndromes." <i>Pain</i> , 73:123-139.	
		Leelanuntakit (1996). "Management of cancer-related pain with transdermal fentanyl" <i>J. Med. Assoc. Thai</i> , Vol. 79(6): 341-346.	
		Martin <i>et al.</i> (1983), "Epidural and intrathecal narcotics." <i>Can. Anaesth. Soc. J.</i> , 30:662-673.	
		Moulin <i>et al.</i> (1992). "Subcutaneous narcotic infusions for cancer pain: treatment outcome and guidelines for use" <i>Can. Med. Assoc. J.</i> , Vol. 146(6): 891-897.	

Examiner Signature	J. J. Thali	Date Considered	6/21/05
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J		Mucha <i>et al.</i> (1990). "Parker and Radow test of drug withdrawal aversion: Opposite effect in rats chronically infused with sufentanil or amphetamine" <i>Pharmacology Biochem. & Behavior</i> , Vol. 35: 219-224.	
		Paix <i>et al.</i> (1995). "Subcutaneous fentanyl and sufentanil infusion substitution for morphine intolerance in cancer pain management" <i>Pain</i> , Vol. 3: 263-269.	
		Satterlee (1991). "Criteria for use of fentanyl citrate, sufentanil citrate, and alfentanil hydrochloride" <i>Clinical Pharmacy</i> , Vol. 10: 635-637.	
		Shaw (1993), "Treatment of intractable cancer pain by electronically controlled parenteral infusion of analgesic drugs." <i>Cancer</i> , 72:3416-3425.	
		Skaer (1993), "Management of pain in the cancer patient." <i>Clin. Ther.</i> , 15:638-649.	
		Slattery <i>et al.</i> (1985), "Newer methods of delivery of opiates for relief of pain." <i>Drugs</i> , 30:539-551.	
		Sjogren <i>et al.</i> (1994). "Disappearance of morphine-induced hyperalgesia after discontinuing or substituting morphine with other opioid agonists" <i>Pain</i> , Vol. 59: 313-316.	
		Taverne <i>et al.</i> (1992). "Comparative absorption and distribution pharmacokinetics of intravenous and epidural sufentanil for major abdominal surgery" <i>Clin. Pharmacokinet.</i> , Vol. 23(3): 231- 237.	
		Van den Hoogen <i>et al.</i> (1987). "Epidural and subcutaneous morphine, meperidine (pethidine), fentanyl and sufentanil in the rat: Analgesia and other <i>in vivo</i> pharmacologic effects" <i>Anesthesiology</i> , Vol. 66: 186-194.	
		Van den Hoogen <i>et al.</i> (1988). "Respiratory effects of epidural and subcutaneous morphine, meperidine (pethidine), fentanyl and sufentanil in the rat" <i>Anesth Analg.</i> Vol. 67: 1071-1078.	
		Vertafridda <i>et al.</i> (1987), "Intraspinal morphine for cancer pain." <i>Acta Anaesthesiol Scand.</i> , 31(85):47-53.	
		Wagner <i>et al.</i> (1997). "Pharmacokinetics and pharmacodynamics of sedatives and analgesics in the treatment of agitated critically ill patients" <i>Clin. Pharmacokinet.</i> Vol. 33(6): 426-453.	
✓		Willens <i>et al.</i> (1993). "Pharmacodynamics, pharmacokinetics, and clinical uses of fentanyl, sufentanil, and alfentanil" <i>Heart & Lung</i> , Vol. 22(3): 239-251.	
Y		Zeiler <i>et al.</i> (1991). "Kontinuierliche peridurale sufentanil-applikation zur postoperativen analgesie" <i>Anaesthesist</i> , Vol. 40: 543-548.	

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